111TH CONGRESS 1ST SESSION

S. 487

To amend the Public Health Service Act to provide for human embryonic stem cell research.

IN THE SENATE OF THE UNITED STATES

February 26, 2009

Mr. Harkin (for himself, Mr. Specter, Mr. Kennedy, Mr. Hatch, Mrs. Feinstein, and Mr. Reid) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To amend the Public Health Service Act to provide for human embryonic stem cell research.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Stem Cell Research
- 5 Enhancement Act of 2009".
- 6 SEC. 2. HUMAN EMBRYONIC STEM CELL RESEARCH.
- 7 Part H of title IV of the Public Health Service Act
- 8 (42 U.S.C. 289 et seq.) is amended by inserting after sec-
- 9 tion 498C the following:

"SEC. 498D. HUMAN EMBRYONIC STEM CELL RESEARCH.

2 "(a) In General.—Notwithstanding any oth	er pro-
--	---------

- 3 vision of law (including any regulation or guidance), the
- 4 Secretary shall conduct and support research that utilizes
- 5 human embryonic stem cells in accordance with this sec-
- 6 tion (regardless of the date on which the stem cells were
- 7 derived from a human embryo).
- 8 "(b) ETHICAL REQUIREMENTS.—Human embryonic
- 9 stem cells shall be eligible for use in any research con-
- 10 ducted or supported by the Secretary if the cells meet each
- 11 of the following:
- "(1) The stem cells were derived from human
- embryos that have been donated from in vitro fer-
- tilization clinics, were created for the purposes of
- fertility treatment, and were in excess of the clinical
- need of the individuals seeking such treatment.
- 17 "(2) Prior to the consideration of embryo dona-
- tion and through consultation with the individuals
- seeking fertility treatment, it was determined that
- the embryos would never be implanted in a woman
- and would otherwise be discarded.
- 22 "(3) The individuals seeking fertility treatment
- donated the embryos with written informed consent
- and without receiving any financial or other induce-
- 25 ments to make the donation.

- 1 "(c) Guidelines.—Not later than 60 days after the
- 2 date of the enactment of this section, the Secretary, in
- 3 consultation with the Director of NIH, shall issue final
- 4 guidelines to carry out this section.
- 5 "(d) Reporting Requirements.—The Secretary
- 6 shall annually prepare and submit to the appropriate com-
- 7 mittees of the Congress a report describing the activities
- 8 carried out under this section during the preceding fiscal
- 9 year, and including a description of whether and to what
- 10 extent research under subsection (a) has been conducted
- 11 in accordance with this section.".
- 12 SEC. 3. ALTERNATIVE HUMAN PLURIPOTENT STEM CELL
- 13 RESEARCH.
- Part H of title IV of the Public Health Service Act
- 15 (42 U.S.C. 284 et seq.), as amended by section 2, is fur-
- 16 ther amended by inserting after section 498D the fol-
- 17 lowing:
- 18 "SEC. 498E. ALTERNATIVE HUMAN PLURIPOTENT STEM
- 19 CELL RESEARCH.
- 20 "(a) In General.—In accordance with section 492,
- 21 the Secretary shall conduct and support basic and applied
- 22 research to develop techniques for the isolation, derivation,
- 23 production, or testing of stem cells that, like embryonic
- 24 stem cells, are capable of producing all or almost all of
- 25 the cell types of the developing body and may result in

- 1 improved understanding of or treatments for diseases and
- 2 other adverse health conditions, but are not derived from
- 3 a human embryo.
- 4 "(b) Guidelines.—Not later than 90 days after the
- 5 date of the enactment of this section, the Secretary, after
- 6 consultation with the Director of NIH, shall issue final
- 7 guidelines to implement subsection (a), that—
- 8 "(1) provide guidance concerning the next steps
- 9 required for additional research, which shall include
- a determination of the extent to which specific tech-
- 11 niques may require additional basic or animal re-
- search to ensure that any research involving human
- cells using these techniques would clearly be con-
- sistent with the standards established under this sec-
- 15 tion;
- 16 "(2) prioritize research with the greatest poten-
- tial for near-term clinical benefit; and
- 18 "(3) consistent with subsection (a), take into
- account techniques outlined by the President's Coun-
- 20 cil on Bioethics and any other appropriate tech-
- 21 niques and research.
- 22 "(c) Reporting Requirements.—Not later than
- 23 January 1 of each year, the Secretary shall prepare and
- 24 submit to the appropriate committees of the Congress a
- 25 report describing the activities carried out under this sec-

- 1 tion during the fiscal year, including a description of the
- 2 research conducted under this section.
- 3 "(d) Rule of Construction.—Nothing in this sec-
- 4 tion shall be construed to affect any policy, guideline, or
- 5 regulation regarding embryonic stem cell research, human
- 6 cloning by somatic cell nuclear transfer, or any other re-
- 7 search not specifically authorized by this section.
- 8 "(e) Definition.—
- 9 "(1) In General.—In this section, the term
- 10 'human embryo' shall have the meaning given such
- term in the applicable appropriations Act.
- 12 "(2) APPLICABLE ACT.—For purposes of para-
- graph (1), the term 'applicable appropriations Act'
- means, with respect to the fiscal year in which re-
- search is to be conducted or supported under this
- section, the Act making appropriations for the De-
- partment of Health and Human Services for such
- 18 fiscal year, except that if the Act for such fiscal year
- does not contain the term referred to in paragraph
- 20 (1), the Act for the previous fiscal year shall be
- deemed to be the applicable appropriations Act.
- 22 "(f) Authorization of Appropriations.—There
- 23 is authorized to be appropriated such sums as may be nec-

- 1 essary for each of fiscal years 2010 through 2012, to carry
- 2 out this section.".

 \bigcirc